

REMARKS

Claims 1, 2, 4, 6-14, 17-22, 24-25, 29-31 are pending in the application.

Please note that in the Office Action Summary dated May 8, 2003, a non-pending claim (original claim 23) is incorrectly stated as a pending claim.

Please amend claim 24 as shown above.

Amendment to Claims

Claim 24 has been amended to correct a typographical error.

Rejections Under 35 U.S.C. §102(b)

Claims 1, 2, 4, 6-14, 17-22, 24-25, 29 and 31 are rejected as anticipated by Yoon, 5,842,971.

The standard for an anticipation rejection is as follows:

“...for anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present.” MPEP 706.02.

Yoon does not teach every aspect of the currently claimed invention.

Applicants respectfully submit that the examiner has not referenced every claimed aspect of the present invention disclosure in the cited art. Particularly, the presently pending claims recite a **drug delivery and dilution** device wherein, in use, a drug at a **first concentration** moves through the elongate body passageway and into the diffusion space, and further wherein fluid from the environment outside the device mixes with the drug, thereby diluting the drug to a **second concentration** within the diffusion space, before said **diluted drug diffuses through the diffuser element to exit the device**.

The Yoon patent teaches an optical endoscope portal for providing a passage through a body cavity wall that includes a cannula comprising an absorbent member 20 having a dry rigid state prior to introduction into the cavity wall and a soft wet state after absorbing fluid.

BEST AVAILABLE COPY

Applicants cannot find within the citations to the Yoon patent by the Examiner (column 9, lines 38-42, 34-44, 42-44, 38-40, 38-44 and the figures) any mention of drug or dilution of a drug from a first concentration to a second concentration within a diffusion space before a diluted drug at a second concentration diffuses through a diffuser element to exit the device as claimed in the present invention.

Rather, the disclosure of Yoon cited by the examiner disclose either passively supplying the absorbent member 20 with fluid via contact with body fluids or actively supplying the absorbent member 20 with fluid via one or more spine members, from externally of the body cavity, without any mention of drug or dilution of a drug, see column 9, lines 33-44.

As such, the citation fails to teach every aspect of the currently claimed invention, and the applicants respectfully request that the rejections should be withdrawn.

Since claims 2, 4, 6-14, 17-22, 29 and 31 depend from claim 1 and recite further limitations of the base claim, these claims are not anticipated by the Yoon reference for the same reasons as cited above for claim 1. Applicants respectfully request that the rejections should be withdrawn.

Since independent claim 25 claims a method for delivery of an reagent to a delivery site in a subject comprising the steps of implanting a drug delivery device as claimed in claim 1, and since claim 24 depends from claim 25 and recites further limitations of the base claim, these claims are not anticipated by the Yoon reference for the same reasons cited above for claim 1. Applicants respectfully request that this rejection should be withdrawn.

Rejections Under 35 U.S.C. §103

Claim 30 is rejected as being unpatentable over Yoon 5,842,971.

Applicants rebut this rejection because it does not meet the standards required to make a prima-face case of obviousness. The legal standards for establishing a prima face case of obviousness is well-established and clearly set out in the MPEP at 706.02(j).

“To establish a prima face case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation ...to modify or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not [be] based on applicant’s disclosure. In re Vaeck, 947 F.2d 488; 20 USPQ2d 1438 (Fed. Cir. 1991).”

The Yoon reference does not teach or suggest all the claim limitations, therefore cannot be used to support a prima facie obviousness rejection. Yoon teaches passively supplying the absorbent member 20 with fluid via contact with body fluids or actively supplying the absorbent member 20 with fluid via one or more spine members, from externally of the body cavity, without any mention of drug or dilution of a drug, see column 9, lines 33-44. Particularly, Yoon does not teach or suggest a **drug delivery and dilution device** wherein, in use, a drug at a **first concentration** moves through the elongate body passageway and into the diffusion space, and further wherein fluid from the environment outside the device mixes with the drug, thereby **diluting the drug** to a **second concentration** within the diffusion space, before said **diluted drug diffuses through the diffuser element to exit the device**.

Further, one of skill in the art would certainly not have a reasonable expectation of success if they tried to apply the Yoon device to practice the present invention. The Yoon device contains an absorbent material that absorbs fluid from the outside, but is completely inadequate for and incapable of diluting a drug within the catheter lumen and then delivering the drug from that lumen.

Thus, a prima face case of obviousness has not been established, and the applicants respectfully request that the rejections should be withdrawn.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact Applicants' Attorney at (408) 864-7435.

Applicants believe that no fee is due at this time. If the Commissioner determines that a fee is necessary, the Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-1953. **A duplicate copy of this communication is enclosed.**

Respectfully submitted,


DURECT CORPORATION

Adam Warwick Bell, D.Phil
Reg. No. 43,490

Signed: 

Dated: 25th June 03

Steven G. Bacsi Ph.D.
Reg. No. 50,736

Signed: 

Dated: 25 June 2003

10240 Bubb Road
Cupertino, CA 95014
Phone: (408) 864-7435
Fax: (408) 777-3577

BEST AVAILABLE COPY